

dermatitis and for the relief of superficial inflammation caused by chemical burns and physical abrasions.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 40932, July 31, 1997; 79 FR 10968, Feb. 27, 2014]

#### § 524.981b Fluocinolone solution.

(a) *Specifications.* The drug contains 0.01 percent fluocinolone acetonide.

(b) *Sponsor.* See No. 099207 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—A small amount of solution is applied to the affected area two or three times daily.

(2) *Indications for use*—(i) *Dogs.* For the relief of pruritis and inflammation associated with otitis externa and certain superficial acute and chronic dermatoses.

(ii) *Cats.* For the relief of pruritis and inflammation associated with acute otitis externa and certain superficial acute and chronic dermatoses.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 40932, July 31, 1997; 79 FR 10969, Feb. 27, 2014]

#### § 524.981c Fluocinolone and neomycin cream.

(a) *Specifications.* The drug contains 0.025 percent fluocinolone acetonide and 0.5 percent neomycin sulfate (0.35 percent neomycin base).

(b) *Sponsor.* See No. 099207 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—A small amount is applied to the affected area two or three times daily.

(2) *Indications for use*—(i) *Dogs.* For the relief of pruritis and inflammation associated with superficial acute and chronic dermatoses. It is used in the treatment of allergic and acute moist dermatitis and nonspecific dermatoses.

(ii) *Dogs and cats.* Used in the treatment of wound infections.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 40932, July 31, 1997; 79 FR 10969, Feb. 27, 2014]

#### § 524.981d Fluocinolone and dimethyl sulfoxide solution.

(a) *Specifications.* Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 20 percent dimethyl sulfoxide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—Instill 1 to 2 milliliters into each anal sac following expression of anal sac contents.

(2) *Indications for use.* For the relief of impaction commonly present in apparently normal anal sacs, for the reversal of inflammatory changes associated with abnormal anal sacs, and to counteract the offensive odor of anal sac secretions.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10969, Feb. 27, 2014]

#### § 524.981e Fluocinolone and dimethyl sulfoxide otic solution.

(a) *Specifications.* Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 60 percent dimethyl sulfoxide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—Instill 4 to 6 drops (0.2 milliliter) twice daily into the ear canal for a maximum period of 14 days. The total dosage used should not exceed 17 milliliters.

(2) *Indications for use.* For the relief of pruritis and inflammation associated with acute and chronic otitis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10969, Feb. 27, 2014]

#### § 524.1005 Furazolidone powder.

(a) *Specifications.* The product contains either 4 or 10 percent furazolidone in inert dispersing agent and propellant.

## § 524.1044

(b) *Sponsors*. (1) See No. 054771 in § 510.600(c) of this chapter for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii), and (c)(3) of this section.

(2) See No. 017135 for use of the 4 percent product as in paragraph (c)(2)(iv) of this section.

(c) *Conditions of use*—(1) *Amount*. Hold container about 6 to 12 inches from the eye or affected area and apply only enough powder to impart a light yellow color.

(2) *Indications of use*—(i) *Dogs*. For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and pyogenic dermatitis.

(ii) *Horses*. For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and following firing (heat or electrocautery).

(iii) [Reserved]

(iv) *Horses and ponies*. For treatment or prevention of bacterial infection of superficial wounds, abrasions, and lacerations caused by *Staphylococcus aureus*, *Streptococcus spp.* and *Proteus spp.* sensitive to furazolidone.

(3) *Limitations*. For topical application in horses, ponies, and dogs: Clean affected area thoroughly, apply drug once or twice daily, and repeat treatment as required. Use only as recommended by a veterinarian in treatment of puncture wounds, wounds requiring surgical debridement or suturing, those of a chronic nature involving proud flesh, generalized and chronic infections of the skin, and those skin conditions associated with intense itching. If redness, irritation, or swelling persists or increases, discontinue use and consult a veterinarian. Do not use in horses intended for human consumption.

[45 FR 49543, July 25, 1980, as amended at 50 FR 30153, July 24, 1985; 56 FR 50653, Oct. 8, 1991; 57 FR 31314, July 15, 1992; 60 FR 55659, Nov. 2, 1995; 65 FR 41588, July 6, 2000; 79 FR 10969, Feb. 27, 2014]

### § 524.1044 Gentamicin ophthalmic and topical dosage forms.

#### § 524.1044a Gentamicin ophthalmic solution.

(a) *Specifications*. Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

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(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in dogs and cats for the topical treatment of infections of the conjunctiva caused by susceptible bacteria.

(2) Administer 1 or 2 drops into the conjunctival sac 2 to 4 times a day.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 14189, Apr. 2, 1976, as amended at 52 FR 7832, Mar. 13, 1987]

### § 524.1044b Gentamicin and betamethasone otic solution.

(a) *Specifications*. Each milliliter of solution contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base and betamethasone valerate equivalent to 1 mg betamethasone alcohol.

(b) *Sponsors*. See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amounts and indications for use*—(i) For the treatment of acute and chronic otitis externa caused by bacteria sensitive to gentamicin in dogs, instill three to eight drops of solution into the ear canal twice daily for 7 to 14 days.

(ii) For the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin in dogs and cats, apply a sufficient amount of the drug to cover the treatment area twice daily for 7 to 14 days.

(2) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006]

### § 524.1044c Gentamicin ophthalmic ointment.

(a) *Specifications*. Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

(b) *Sponsors*. See Nos. 000061 and 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Apply approximately a 1/2-inch strip to the affected eye 2 to 4 times a day.

(2) *Indications for use*. For treatment of conjunctivitis caused by susceptible bacteria.